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IN THE
Supreme Court of the United States

APPLERA CORP. AND TROPIX, INC.,
Petitioners,

v.

ENZO BIOCHEM, INC., ENZO LIFE SCIENCES, INC., AND YALE UNIVERSITY,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF

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REPLY BRIEF

Applera's petition demonstrates that the Federal Circuit's standard for indefiniteness—under which a patent's claims need merely be "capable of construction" and therefore not "insolubly ambiguous," Pet. 18-22—is fundamentally inconsistent with 35 U.S.C. § 112, which requires that claims be "particular[ ]" and "distinct[ ]." Whereas this Court requires "precision" and clarity, Pet. 16-18, here, the Federal Circuit was satisfied with merely "some guidance," Pet. App. 14a. Enzo says little about the question actually presented by the petition. It does not deny that the "capable of construction" test governs in the Federal Circuit. It does not even deny that that test is inconsistent with this Court's precedents.

Instead, Enzo answers a different question entirely—whether § 112 "precludes the use of relative terms." BIO i. This argument is the heart of Enzo's case against certiorari, see *infra* at 5, but that question is not remotely presented. The petition nowhere suggests that words of degree are indefinite per se—and of course not; Applera's own patents use such terms, BIO 25-26—which is why Enzo never once provides a page citation to the petition in attacking this straw man. Its other principal argument is that patent claims do not define an invention. See *infra* at 2-5. Over a century of this Court's cases hold otherwise. That the Federal Circuit's jurisprudence has reached the point where a litigant could make this argument with a straight face is the best evidence of the need for this Court's review.

The real question presented is whether the Federal Circuit's approach to a critical patent doctrine has departed, again, from the words of the statute. It has, and review is sorely needed. This question is vi-

tally important, as the amici supporting Applera have explained, and it is recurring—it governs every patent's validity and construction. The Federal Circuit's standard is at odds with the statute's text and purposes, and this Court's precedents interpreting it, and has been rejected by the PTO and called into question by the Department of Justice. The petition should be granted.

ARGUMENT

I. THE FEDERAL CIRCUIT HAS DEPARTED FROM THE TEXT OF § 112 AND THIS COURT'S PRECEDENTS CONSTRUING IT.

Enzo does not attempt to reconcile the Federal Circuit's indefiniteness standard with the statutory text. It does not defend the "capable of construction" test, nor the "insolubly ambiguous" iteration of it. Instead, it offers a vision of patent claiming so radical that it confirms the case for certiorari, and addresses questions that are not presented.

1. Enzo turns to the "origins" of the claiming requirement to argue that the inventor need not inform the public of an invention's boundaries, but must only distinguish the claimed invention from the prior art. BIO 2-3, 12, 17-20. Even if this argument were correct, and it is not, Enzo never explains how it would support the Federal Circuit's "capable of construction" test. It therefore is no argument against certiorari.

On its merits, this argument is contrary to the most basic requirements of the Patent Act. Never has this Court held that a patent's only purpose is to distinguish the claimed invention from the prior art. Rather, the claims serve a fundamental notice function: "The inventor must 'inform the public during the life of the patent of *the limits of the monopoly as-*

serted....'" *Gen. Elec.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938).[1] This is so everyone will know "which features may be safely used or manufactured without a license and which may not." *Permutit* v. *Graver Corp.*, 284 U.S. 52, 60 (1931).

Accordingly, the claims must *both* distinguish the invention from the prior art and demarcate the invention's boundaries: "The statutory requirement of particularity and distinctness in claims is met only when they clearly distinguish what is claimed from what went before in the art *and* clearly circumscribe what is foreclosed from future enterprise." *United Carbon* v. *Binney & Smith*, 317 U.S. 228, 236 (1942). Enzo does not explain what purpose would be served by a patent that does not tell the public what the invention is, a notion counter to both common sense and this Court's decisions. *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002) ("A patent holder should know what he owns, and the public should know what he does not."); *GE*, 304 U.S. at 369 (the "limits of a patent must be known").

The extreme nature of Enzo's argument is laid bare by its attack on the claiming requirement. It derides as "court-made" the requirement "that the claims 'define' the invention." BIO 20. That is not this Court's view, which explained 125 years ago that "[t]he claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is." *White* v. *Dunbar*, 119 U.S. 47, 52 (1886); see *Markman* v. *Westview Instr.*, 517 U.S. 370,

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[1] Emphases added throughout unless otherwise noted.

373 (1996) ("[t]he claim 'define[s] the scope of a patent grant'").[2]

Cases like *Permutit* and *GE* demonstrate the error in Enzo's argument that patent claims need not provide "a blueprint for circumvention." BIO 1, 17, 19. The claims indeed are meant to give the public clear notice of "which features may be safely used or manufactured without a license and which may not." *Permutit*, 284 U.S. at 60. While Enzo denigrates this as a "blueprint for circumvention," its own principal authority explains that "[i]ndefiniteness is objectionable because the patent does not disclose to the public how the discovery ... can be made useful *and how its infringement may be avoided*." *Eibel Process* v. *Minn. & Ont. Paper*, 261 U.S. 45, 65 (1923); see *McClain* v. *Ortmayer*, 141 U.S. 419, 424 (1891) (claims "apprise the public of what is still open to them").

Enzo further argues that claims need not be *that* precise—merely "'sufficiently definite to guide those skilled in the art to its successful application.'" BIO 1, 13 (quoting *Minerals Separation* v. *Hyde*, 242 U.S. 261, 271 (1916)). But *Minerals Separation* did not overturn this Court's numerous precedents requiring precision and clarity, nor has any decision so understood it. To the extent there were tension between *Minerals Separation* and those other decisions, that would be more reason to grant the petition, not less. Enzo similarly justifies ambiguous claiming on the theory that some uncertainty already is created by the doctrine of equivalents. BIO 16-17, 20-21. This

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[2] That claim language may be interpreted in light of other parts of the patent, BIO 21, is not in dispute. *See Phillips* v. *AWH Corp.* 415 F.3d 1303, 1316-19 (Fed. Cir. 2005) (en banc). Nor has Applera ever argued that *any* ambiguity in claim construction gives rise to indefiniteness. BIO 16.

has matters backwards. It is precisely because of the potential for such uncertainty that that doctrine has been carefully circumscribed. *Warner-Jenkinson* v. *Hilton Davis Chem.*, 520 U.S. 17, 29 (1997). It also is why cases arising under that doctrine contain some of this Court's strongest statements about the need for clear claims. Pet. 17; *Festo*, 535 U.S. at 730-32 ("The [patent] monopoly is a property right; and like any property right, its boundaries should be clear."); *Warner-Jenkinson*, 520 U.S. at 29.

2. Next, Enzo argues, certiorari should be denied because this Court has not forbidden the use of terms of degree like "substantially." BIO 1-2, 25. And, it notes, words of degree commonly are used. *Id.* at 1-2, 12-14. This is the reddest of red herrings. Nowhere has Applera argued that words of degree are indefinite per se. Rather, they can lend themselves to indefiniteness when, as here, they are not clearly defined. *Eibel Process*, upon which Enzo repeatedly relies, held the terms "high" and "substantial" definite only because the description of the invention was sufficiently specific to permit the public to discern "how the discovery ... can be made and how its infringement could be avoided." 261 U.S. at 65. *United Carbon*, decided after *Eibel*, held that claims employing the term "substantially" were indefinite because the invention was not "accurately defined." 317 U.S. at 237. Nothing in the petition advocates or would require that *Eibel Process* be "overturn[ed]." BIO 26.

Notably, Enzo is forced to acknowledge that the three other cases it relies on to defend terms of degree did not even address indefiniteness. BIO 15 n.3. Rather, Enzo says, if those claim terms were indefinite, this Court would have said so sua sponte. That, of course, is directly contrary to this Court's usual practice.

3. Enzo all but ignores the state of the law in the Federal Circuit. Enzo does not dispute that the "capable of construction" test is circuit law. Pet. 19 (citing cases). It does not address or defend the Federal Circuit cases, discussed in the petition, which employ that test. *Compare* Pet. 18-19, *with* BIO v-viii. It does not dispute that, in evaluating whether a claim is "capable of construction," the Federal Circuit commonly asks whether a claim is "insolubly ambiguous." Pet. 19 (citing cases). Perhaps most telling, Enzo never even argues that the Federal Circuit's test is consistent with the statutory language or this Court's interpretation of it.

Instead, Enzo observes, the Federal Circuit did not recite the words "insolubly ambiguous" here. BIO 2, 13-14. But the Federal Circuit undisputedly employed the "capable of construction" test, see Pet. 11, 26; Pet. App. 10a, of which the "insolubly ambiguous" formulation is part. Enzo suggests that the decision below employed a less objectionable test—whether "'those skilled in the art would understand what is claimed.'" BIO 10, 13 (quoting Pet. App. 11a). But the panel quoted that language from *Young* v. *Lumenis*, which holds that claims are indefinite only when they are "'not amenable to construction or are insolubly ambiguous,'" 492 F.3d 1336, 1346 (Fed. Cir. 2007); and it relied on *Datamize, LLC* v. *Plumtree Software*, which holds likewise, 417 F.3d 1342, 1347-48 (Fed. Cir. 2005). Pet. App. 11a. Like the panel's determination that claims are definite when they provide merely "some guidance," Pet. App. 14a, *Young* likewise found claims definite because they could "'be given any reasonable meaning.'" 492 F.3d at 1346. Neither formulation is remotely consistent with the "particular[ity] and distinct[ness]" required by the statute.

Enzo elsewhere argues that definiteness remains a "powerful tool" in the Federal Circuit. BIO 27. Its flimsy examples prove the opposite. *Quantum Corporation* v. *Rodime* did not address indefiniteness at all, but rather considered whether the claims were impermissibly broadened during reexamination. 65 F.3d 1577, 1580 (Fed. Cir. 1995). *Acacia Media Technologies Corporation* v. *New Destiny Internet Group* is one unpublished decision by one district court, which was affirmed in an unpublished order by the Federal Circuit. See BIO 27. By contrast, a recent study of Federal Circuit decisions confirms that, when the issue is breadth of terminology (rather than a technical defect), claims rarely are held indefinite. Altera Br. 11 & n.3. Enzo quibbles about the precise figures in the article (BIO 27), but cannot identify a single Federal Circuit decision that employs the definiteness doctrine in a meaningful fashion.

That is why it is necessary for this court to intervene. As Enzo itself acknowledges, "[f]or a decade, the Federal Circuit has employed its current standards without meaningful dispute or dissent." BIO 25. Judge Plager may not be an "active judge," *id.* at 3, 17, but he is experienced and has accurately explained the serious problem in the Federal Circuit's jurisprudence, and no other judge on that court will take action. As in *KSR International* v. *Teleflex*, 550 U.S. 398, 412-14 (2007)—where the Federal Circuit adopted an atextual invalidity test, and *no* Federal Circuit judge (active or senior) voiced dissent—review by this Court is the only option to restore definiteness to its moorings.

The erroneous Federal Circuit test is of abiding importance to the proper application of the patent laws. The requirement of definiteness applies to every claim in every patent, and a feckless indefiniteness

test creates perverse incentives for drafting overly broad claims, to the detriment of the public. See Pet. 17-18; S. Jay Plager, *The Federal Circuit As An Institution: Of Uncertainty and Policy Levers*, 43 Loyola L.A. L. Rev. 749, 758-59 (2010). As the FTC recognized in its seminal 2003 report, "questionable patents are a significant competitive concern and can harm innovation." *To Promote Innovation: The Proper Balance Of Competition and Patent Law and Policy*, exec. summ. 5 (2003) (capitalization omitted). Companies avoid researching in or entering fields covered by such questionable patents, and engage in defensive patenting. *Id.* at 5-7. As the array of *amicus* corporations supporting the petition explain, such patents incentivize litigation by patent trolls, leaving companies vulnerable to coercive and expensive settlements. Yahoo Br. 13-14; Altera Br. 15-16. That Yale itself is not a troll, BIO 27 n.8, is irrelevant; this issue is important because patent trolls can and do exploit the uncertainty caused by the Federal Circuit's test.

II. THE FEDERAL CIRCUIT'S INTERPRETATION OF § 112 CONFLICTS WITH THE PTO'S.

The Federal Circuit and the PTO employ different tests for definiteness. Pet. 23-26. Enzo does not dispute this; it responds that this approach is justified by the difference between pre-issuance and post-issuance review. BIO 22. But the petition itself notes this justification, as did the PTO in *Ex parte Miyazaki*. Pet. 24. The question is whether the differing standards can be squared with the fact that both the PTO and the Federal Circuit are applying the same statutory text. Enzo contends that an applicant can amend its claims to "'more clearly and precisely define'" the invention's boundaries only be-

fore the patent issues. BIO 22. On the contrary, defects in already-issued claims can be cured through reexamination, or through the reissue process of 35 U.S.C. § 251, see *Keystone Bridge* v. *Phoenix Iron*, 95 U.S. 274, 278-79 (1877); *Merrill* v. *Yeomans*, 94 U.S. 568, 573 (1876).[3] More to the point, whatever the BPAI's rationalization for differing standards, the United States seems to question the Federal Circuit test—as evidenced by the brief it filed on rehearing en banc in *Ariad*. Pet. 25. On this point, Enzo offers no response. At a bare minimum, therefore, the Court should seek the views of the United States.

Finally, Enzo asserts that there is no conflict because the PTO and the Federal Circuit both concluded here that the claims were definite. BIO 24-25, 29. But the PTO allowed the claims at least a decade before the BPAI decided *Miyazaki*. BIO App. 1a.

III. THE DECISION BELOW IS AN EXCELLENT VEHICLE FOR RESOLVING THESE ISSUES.

The gross ambiguity of Enzo's patents makes this case a particularly good vehicle for addressing the important question presented. Pet. 26-29. For the Federal Circuit, the claims were definite because of mere examples in the specification and dependent claims. Pet. App. 17a (one can perform tests to "see whether they fall within the range of exemplary values disclosed"). Those examples, however, do not demarcate a floor or ceiling for what the claims

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[3] Enzo also argues that the PTO and the Federal Circuit apply different standards in certain contexts. BIO 23-24. But the examples it cites principally concern burdens of proof rather than substantive tests, for which the PTO and Federal Circuit otherwise do use the same tests, Pet. 24 n.10, and it offers no other example where they interpret the statute differently.

purport to cover. Pet. 26-27. Importantly, Enzo does not contend otherwise. Cf. BIO 14.

Instead, Enzo disparages Applera's indefiniteness argument as a request that Enzo's patent "tell [Applera] how to build around [the patent] by making a molecule that would not work." BIO 31; *id.* at 4. On Enzo's theory, the "claims would cover any interactions which succeed, but not those which do not—rendering 'substantial' a nullity." Pet. App. 58a.[4] It is Enzo's job to tell the public what it thinks would "work." This case illustrates why that is important: The linkage group used by Applera interferes somewhat with hybridization—just not so much as to prevent it entirely—and indeed some interference is affirmatively helpful to the Applera system. Defendants' Opposition at 12, No. 04-CV-929 (D. Conn. Mar. 26, 2007) (Dkt. 216). It therefore is critical to know the bounds of what Enzo thinks "work[s]." Any other approach is profoundly anticompetitive and harmful to consumers.

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[4] Elsewhere, however, Enzo suggests that its patents do *not* contain functional claims, but rather specify "concrete chemical structure." BIO 30. This is simply incorrect. The patent discloses a generic structural configuration, but (as the Federal Circuit recognized) the linkage group at issue here is recited in functional terms. Pet. App. 4a; Pet. 9-10 & n.6. The letter to the PTO cited by Enzo says nothing about the linkage group, its structure, or the limits thereof. BIO 30 (citing BIO App. 51a).

Enzo asserts in passing that Applera has waived any argument about functional claim language. BIO 29-30 & n.11. The functional nature of the claim language is not, however, a separate, waivable issue. This Court repeatedly has warned about the potential overbreadth of functional claims, *see* Pet. 27 & n.12, and here the indefiniteness problem is exacerbated because the word of degree appears within functional claim language. Applera has so argued throughout. *E.g.*, CAFC Red Br. 32-35.

Finally, Enzo notes that this case is interlocutory. BIO 31-32. But that is no obstacle to review "where the opinion of the court below has decided an important issue, otherwise worthy of review, and Supreme Court intervention may serve to hasten or finally resolve the litigation." Eugene Gressman et al., *Supreme Court Practice* 282 (9th ed. 2007) (citing cases). Indefiniteness is an issue of law reviewed de novo, see Pet. App. 9a; it has been finally adjudicated; and, if reversed, it will resolve this litigation. Further proceedings on remand would not assist this Court's review. The Court has reviewed patent cases in the same posture. *E.g.*, *KSR*, 550 U.S. at 412-14 (reviewing decision reversing summary judgment of invalidity).

CONCLUSION

For the foregoing reasons and those in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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